administering to a patient in need thereof a composition comprising a fusion protein, wherein the fusion protein comprises a first protein comprising a non-toxic, proteolytic fragment of tetanus toxin (TT) recombinantly fused to a second protein, wherein the non-toxic, proteolytic fragment of tetanus toxin comprises a fragment C and at least the 11 amino acid residues of fragment B that immediately precede the amino terminus of fragment C, and wherein the fusion protein undergoes *in vivo* retrograde axonal transport and transynaptic transport when administered to the patient, wherein the fusion protein effectively treats said patient.

REMARKS

Applicants respectfully request reconsideration and further examination in view of the following remarks.

Claims 1-5 and 8-37 are pending in this application. Claims 12-30 stand withdrawn from consideration as being directed to a non-elected invention.

Claim 31 was amended to recite "wherein the fusion protein effectively treats said patient," as suggested by the Examiner, and as discussed in further detail below.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing the pending claims in condition for allowance. Applicants submit that the proposed amendment does not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

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Information Disclosur Statement

Applicants previously noted that because EP 0030496 is related to the same family as two Canadian applications, CA 1152493 and CA 1178949, these Canadian applications can serve as the English translation of EP 0030496. In Paper No. 13, the Office states that EP 0030496 will be considered to the extent that CA 1152493 and CA 1178949 are accurate translations of EP 0030496. The Office requests a copy of the PTO form 1449, so it can make its consideration of EP 0030496 of record. As requested, applicants submit with this response a copy of the PTO 1449 form, previously submitted on May 9, 2000.

Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office rejects claims 31 and 34-37 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention. (Paper No. 13, p. 3, ¶ 5). According to the Office, claim 31 is directed to a method for treating a CNS disease comprising administering a fusion protein, "yet the claim fails to recite a step or steps that lead back to and accomplish the goal set forth in the preamble of the claim." *Id.* The Office suggests that the phrase "wherein the fusion protein effectively treats said patient," would obviate the rejection. *Id.*

Applicants do not agree that the suggested phrase is required to make explicit what is already implicit in the claims. Nevertheless, in an effort to facilitate prosecution, applicants have amended claim 31 to recite the suggested phrase. Applicants thank the Examiner for his suggestion and request that this rejection be withdrawn.

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Rejections Under 35 U.S.C. § 103

(1) Rejections based on U.S. Patent No. 5,780,024

(a) Claims 1-8, 11, 31, 34, 36, and 37

The Office rejects claims 1-8, 11, 31, 34, 36, and 37 under 35 U.S.C. § 103 as allegedly obvious over U.S. Patent No. 5,780,024 ("the '024 patent") in view of Fairweather et al. (Paper No. 13, pp. 4-7, ¶ 9). The Office asserts that the '024 patent teaches an *in vivo* method for delivery of a composition comprising the tetanus toxin C fragment recombinantly fused to a second protein (SOD-1). (*Id.* at 4). The Office further asserts that the '024 patent demonstrates that "the fusion protein is capable of in vivo retrograde axonal transport and transynaptic transport in to [sic, into] the CNS (e.g., from systemic administration to the brain stem, see col 1)." (*Id.*) Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the reference (or references when combined) must teach or suggest all elements of the claim. *See* M.P.E.P. § 2143.

The Office has not established a *prima facie* case of obviousness for at least two reasons. First, the references, when combined, do not teach or suggest every element of the claims. Second, there is no motivation to combine the references. Applicants will address each of these reasons in turn.

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Independent claims 1 and 31 recite that the fusion protein undergoes *in vivo* transynaptic transport. Neither the '024 patent nor Fairweather et al. disclose *in vivo* transynaptic transport of a fusion protein.

Without support, the Office asserts that one of ordinary skill in the art would appreciate that the "in vivo retrograde transport" referred to in the '024 patent "includes both retrograde axonal transport and retrograde transsynaptic transport." (*Id.* at 6). As demonstrated in the specification, however, the art recognizes a clear distinction between *in vivo* retrograde transport and *in vivo* transynaptic transport.

> The axonal retrograde transport begins at the muscle level, where the composition of interest is taken up at the neuromuscular junction, and migrates to the neuronal body of the motoneurons (which are also called the first order neurons) in the CNS or spinal cord. First order neurons mean neurons that have internalized the composition of interest, and thus in this case, correspond to motoneurons.
>
> The transynaptic retrograde transport corresponds to interneuron communications via the synapses from the motoneurons, and comprises second order neurons and higher order neurons (fourth order corresponding to neurons in the cerebral cortex).

Specification, page 12.

Thus, the specification distinguishes between transport across the synapse that connects two neurons (i.e., transynaptic transport) and the uptake of compositions by a motoneuron at the neuromuscular junction followed by migration through the motoneuron (i.e., axonal retrograde transport). The '024 patent does not disclose transynaptic transport of the SOD-1/TTC fusion protein.

The '024 patent insinuates that the SOD-1/TTC fusion protein may be transported from the peripheral nervous system in to the CNS "[b]y virtue of TTC-

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mediated uptake by neurons, retrograde axonal transport within neurons, *and* retrograde transsynaptic transfer between neurons[.]" Col. 4, lines 37-43 (emphasis added). But the '024 patent does not demonstrate any such transynaptic transport. Column 16 of the '024 patent describes an experiment allegedly showing the uptake and retrograde axonal transport of a SOD-1/TTC fusion protein in motor neurons. Following intramuscular injection of the SOD-1/TTC fusion protein into the tongue, the fusion protein was observed in the cell bodies of the tongue motor neurons. Col. 16, lines 14-36. This experiment thus demonstrates uptake of the fusion protein into tongue motor neurons through the neuromuscular junction, i.e., axonal retrograde transport. But the experiment does not demonstrate transport of the fusion protein between two neurons. Thus, it does not show transynaptic transport of the fusion protein.

Rather, applicants were the first to demonstrate *in vivo* transynaptic transport using a fusion protein containing a tetanus toxin fragment. For example, as explained in the specification, following administration of applicants' β-gal-TTC fusion protein, β-galactosidase activity was detected in the hypoglossal nucleus, i.e., the tongue motor neurons (Example 7) *and* also in connected neurons of the brainstem areas (Example 8). Specification, pages 26-31. Accordingly, the '024 patent does not teach or suggest transynaptic transport of the fusion protein. Fairweather et al. fail to remedy the deficiencies of the '024 patent. For this reason alone, applicants respectfully request withdrawal of this 35 U.S.C. § 103 rejection.

Even assuming that the '024 patent teaches or suggests *in vivo* transynaptic transport of the SOD-1/TTC fusion protein, the Office has failed to establish a *prima*

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facie case of obviousness because there is no motivation to combine the teachings of the '024 patent with the teachings of Fairweather et al.

Independent claims 1 and 31 recite that the tetanus toxin portion of the fusion protein comprises a fragment C and at least the 11 amino acid residues of fragment B that immediately precede the amino terminus of fragment C. The Office acknowledges that the '024 patent does not disclose a tetanus toxin fragment that includes **at least the 11 amino acid residues of fragment B immediately preceding the amino terminus of fragment C**. (Paper No. 13, p. 5). The Office asserts, however, that the '024 patent "disclose[s] embodiments having 2 or 8 additional amino acids (col. 6) and indicate that more or less are encompassed by the invention." (*Id.*) The Office also asserts that Fairweather et al. disclose a recombinant tetanus toxin fragment C including at least 11 amino acids of fragment B (i.e., pTet18).[1] (*Id.*) Therefore, according to the Office, "it would have been obvious to one of ordinary skill in the art, at the time the invention was made, with reasonable expectation of success to use a Tet C fragment with at least 11 amino acids of the B fragment (as taught by Fairweather), or simply 11 additional amino acids as suggested by [the '024 patent]." (*Id.*)

The Office further asserts that the motivation to combine the references is provided by the references themselves. (*Id.*) Applicants respectfully assert that there is no motivation in the references themselves to combine the reference teachings.

Fairweather et al. immunized mice with various tetanus toxin constructs, including a nonrecombinant fragment C (451 amino acids), a recombinant 441 amino

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[1] As discussed below, pTet18 is a tetanus toxin construct containing fragment C and the last 121 amino acids of fragment B

acid portion of fragment C fused to part of the *E. coli* trpE protein (pTet11), and a recombinant fragment C plus the last 121 amino acids of fragment B (pTet 18). Fairweather et al. investigated whether these tetanus toxin constructs induced the formation of neutralizing antibodies in mice; the reference suggests nothing about using these tetanus toxin constructs to mediate *in vivo* retrograde axonal transport or transynaptic transport. Thus, Fairweather et al., who investigated the immunological properties of these tetanus toxin constructs, provide no motivation to use the pTet18 tetanus construct in a method for delivering a fusion protein into the CNS, as discussed in the '024 patent.

The Office alleges that the motivation to combine references can be found in Fairweather et al., which allegedly teach that the pTet18 tetanus toxin was easier to obtain than a protein containing only fragment C of the tetanus toxin (i.e., pTet11). (Paper No. 13, p. 5). There is no indication in the '024 patent, however, that the fusion proteins disclosed therein were difficult to obtain. Indeed, obtaining the desired fusion protein appears straightforward. Col. 5, lines 27-55.

Furthermore, the pTet11 construct of Fairweather et al. is not a "protein containing only the C fragment" of the tetanus toxin, as asserted by the Office. (*Id.*) The pTet11 construct is missing 10 amino acid residues of fragment C, and there is no evidence that such a construct retains the properties of the full-length fragment C protein. Thus, one can not draw conclusions about the properties of pTet18 relative to the fragment C-containing hybrid proteins of the '024 patent, based on comparisons in Fairweather et al. between pTet18 and pTet11, which does not even contain a full-length fragment C.

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Furthermore, Fairweather et al. actually teach away from the claimed invention. As discussed above, Fairweather et al. compared the immunological properties of pTet11 and pTet 18. The pTet11 construct contained a portion of the tetanus toxin fragment C fused to the *E. coli* trpE protein. On the other hand, Fairweather et al. selected the pTet18 construct, because it "does not carry any *trpE* sequences." (Fairweather et al., p. 2542, col. 2, second full paragraph). In other words, unlike the pTet11 construct, the pTet18 construct, did not encode a fusion protein. The claimed invention, however, is directed to the administration of a fusion protein, not simply a tetanus toxin fragment. Thus, Fairweather et al., who wanted to examine the immunological properties of a recombinant tetanus toxin fragment, pTet18, which was not fused to a second protein, actually teach away from the claimed invention.

Moreover, modifying the pTet18 construct by fusing it to a second protein, would render the pTet18 construct unsatisfactory for its intended purpose. *See* M.P.E.P. § 2143.01. If a second protein were fused to the tetanus toxin fragment of the pTet18 construct, it would defeat Fairweather et al.'s goal of measuring the antibody response to a recombinantly produced tetanus toxin fragment that was not fused to another protein. Accordingly there is no motivation to combine the teachings of the '024 patent with Fairweather et al.

The Office further asserts that the '024 patent (Col. 5, paragraph bridging Col. 6) references the Fairweather laboratory as a source of material for practicing the invention. (Paper No. 13, p. 7). Column 5 of the '024 patent cites a Fairweather et al. article that discloses the cloning and expression of the tetanus toxin fragment C. This is not the same Fairweather et al. article that the Office has cited in its 35 U.S.C. § 103

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rejection, and therefore, does not provide the necessary motivation to combine a separate Fairweather et al. article with the '024 patent.

Finally, the Office further asserts that the motivation to combine the references may be found in the '024 patent based on the alleged teaching that additional amino acids may be added to fragment C as a matter of routine optimization. (Paper No. 13, p. 5). The '024 patent states that "[a]dditional amino acid residues may be present at the ends of the hybrid protein moieties without disrupting hybrid protein function. Such optional additional amino acid residues may be artifacts of the plasmid construction process, and may be left in place as a matter of convenience." Col. 6, lines 38-42. Thus, the '024 patent does not teach adding amino acids to fragment C as a matter of routine optimization. Rather the '024 patent indicates that, as a matter of convenience, additional amino acids can be present at the ends of the hybrid protein moieties, provided they do not disrupt the function of the hybrid protein. This statement in the '024 patent provides no motivation to combine the teachings of the '024 patent with Fairweather et al., particularly since Fairweather et al. is silent with respect to the function of the pTet18 construct, i.e., whether the pTet18 construct "retains the neuronal binding and uptake properties of the holotoxin without the toxic domains." Col. 1, lines 64-67. Thus, any alleged motivation to combine these references based on the '024 patent is inappropriate hindsight reconstruction based solely on the teachings of the present specification. *See In re Dow Chemical Co.*, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988).

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(b) Claims 36 and 37

In addition to the reasons discussed above, applicants respectfully assert that the '024 patent, in view of Fairweather et al., does not render claims 36 and 37 obvious for the additional reasons discussed below.

Claim 36 depends from claims 1 and 31 and recites that the fusion protein comprises an amino acid sequence comprising SEQ ID NO:16. Neither the '024 patent nor Fairweather et al. disclose an amino acid sequence comprising SEQ ID NO:16. Thus, the cited references do not teach or suggest every element of claim 36.

Claim 37 depends from claims 1 and 31 and recites that the non-toxic, proteolytic fragment of tetanus toxin consists of a fragment C and the 11 amino acid residues of fragment B that immediately precede the amino terminus of fragment C. Neither the '024 patent nor Fairweather et al. disclose a tetanus toxin consisting of a fragment C and the 11 amino acid residues of fragment B that immediately precede the amino terminus of fragment C.

"When there is a specific, structurally related prior art compound, the question of obviousness is whether the prior art suggested the specific modifications necessary to achieve the claimed compound." *Board of Regents of the University of Washington v. Eli Lilly & Co.*, 2002 WL 1305996, *17 (Bd. Pat. App. & Interf.) (finding that one cDNA sequence did not render obvious a second cDNA sequence differing by only two nucleotides, because there was no suggestion in the sequences themselves, or the prior art, to modify the two nucleotide positions that differed).[2] Here, neither the '024 patent nor Fairweather et al. suggest modifying either the pTet18 tetanus toxin construct

[2] A copy of this recent Board decision is attached as Exhibit 1.

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of Fairweather et al. or the TTC fragment of the '024 patent to obtain a tetanus toxin consisting of a fragment C and the 11 amino acid residues of fragment B that immediately precede the amino terminus of fragment C, as claimed. Thus, the cited references do not teach or suggest every element of claim 37.

Accordingly, for these additional reasons, applicants respectfully request that this 35 U.S.C. § 103 rejection be withdrawn from claims 36 and 37.

(c) Remaining Claims

The Office also made the following rejections under 35 U.S.C. § 103 based on the '024 patent:

1. Claims 9 and 10 were rejected as allegedly obvious over the '024 patent in view of Fairweather et al., as applied to claims 6-8, 11, and 31, and further in view of Fishman. (Paper No. 13, pp. 8-9, ¶ 10).

2. Claims 1-8, 11, 31, and 33-36 were rejected as allegedly obvious over the '024 patent in view of Fairweather et al., as applied to claims 1-8, and further in view of U.S. Patent No. 6,159,948. (Paper No. 13, pp. 9-10, ¶ 11).

Applicants respectfully traverse each of these rejections.

As discussed above, the '024 patent does not disclose *in vivo* transynaptic transport of a fusion protein containing a tetanus toxin fragment. The remaining references relied on by the Office, Fishman et al.[3] and U.S. Patent No. 6,159,948, fail to

[3] The Office asserts that Fishman et al. teach *in vivo* transynaptic transport of a fusion protein, because Fishman et al. state that "[l]inkage with [tetanus toxin C fragment] also **may** enhance the stability of a chosen protein within the CNS as well as promote its spread by transsynaptic transport." (Paper No. 13, p. 13 (emphasis added)). This statement does not demonstrate *in vivo* transynaptic transport of a tetanus toxin fragment C fusion protein. It is mere speculation. Furthermore, as

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remedy the deficiencies of the '024 patent. None of these secondary references teaches or suggests the *in vivo* transynaptic transport of a fusion protein containing a tetanus toxin fragment. In addition, as discussed above, there is no motivation to combine the '024 patent with Fairweather et al. Accordingly, applicants respectfully request withdrawal of these 35 U.S.C. § 103 rejections.

(2) Rejections based on Francis et al.

(a) Claims 1-8, 11, 31, 34, 36, and 37

The Office rejects claims 1-8, 11, 31, 34, 36, and 37 under 35 U.S.C. § 103 as allegedly obvious over Francis et al., in view of Fairweather et al. (Paper No. 13, pp. 10-12, ¶ 13). Applicants respectfully traverse this rejection.

The Office asserts that Francis et al. teach an *in vitro* method for delivery of a composition comprising the tetanus toxin C fragment recombinantly fused to a second protein (SOD-1)[4]. (*Id.* at 10). The Office acknowledges that Francis et al. do not disclose an *in vivo* method for delivering the fusion protein, however, the Office asserts that Francis et al. propose such an *in vivo* delivery method. (*Id.* at 11). For example, the Abstract states that "SOD:Tet451 may prove to be a useful agent for the targeted delivery of SOD-1 to neurons." Therefore, the Office asserts that it would have been obvious to one of ordinary skill in the art to use the *in vitro* method of Francis et al. in an

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discussed in the specification, while others have shown that the tetanus toxin fragment C can undergo retrograde transport, they have not demonstrated that it can undergo *in vivo* transynaptic transport. (Specification, pp. 2-4).

[4] Applicants note that the authors of Francis et al. are the same as the named inventors of the '024 patent and that the SOD:Tet451 fusion protein disclosed in Francis et al. appears to be the same as the SOD:Tet451 fusion protein disclosed in the '024 patent.

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in vivo method, as required by the claims, with a reasonable expectation of success. (*Id.*) Applicants respectfully traverse this rejection.

Francis et al. do not disclose *in vivo* transynaptic transport of a fusion protein containing a tetanus toxin fragment, as recited in the claims. The Office believes otherwise, relying on the following passage from Francis et al. for teaching that the SOD-1/TTC fusion protein underwent *in vivo* transynaptic transport.

> Even with a normally functioning blood-brain barrier, the selective uptake of SOD:Tet451 by motor neurons in the spinal cord and brainstem **could be a potential route** for delivering SOD-1 to motor neurons in disorders such as ALS. Through this pathway, the hybrid protein **could** access other central nervous system neurons as well, given the ability of TTC to undergo retrograde trans-synaptic transfer.

Francis et al., p. 15441, col. 1, first full paragraph (emphasis added).

But this passage from Francis et al. refers to the ability of the tetanus toxin C fragment to undergo *in vivo* transynaptic transport, not the SOD:Tet451 fusion protein. Furthermore, as discussed in the specification, while others have shown that the tetanus toxin fragment C can undergo retrograde transport, they have not demonstrated that it can undergo *in vivo* transynaptic transport. (Specification, pp. 2-4). Rather, applicants were the first to demonstrate *in vivo* transynaptic transport using a fusion protein containing a tetanus toxin fragment. Therefore, Francis et al. do not disclose *in vivo* transynaptic transport of a fusion protein containing a tetanus toxin fragment, as recited in the claims. Fairweather et al. do not remedy the deficiencies of Francis et al. Accordingly, applicants respectfully request withdrawal of this 35 U.S.C. § 103 rejection.

In addition, applicants respectfully assert that the Office has not established a prima facie case of obviousness because there is no motivation to combine Francis et

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al. with Fairweather et al. The Office acknowledges that Francis et al. do not teach adding at least 11 amino acids of the tetanus toxin fragment B to the tetanus toxin fragment C. (*Id.*) The Office, however, asserts that Fairweather et al. disclose a recombinant tetanus toxin fragment C including at least 11 amino acids of fragment B (i.e., pTet18). As above with the § 103 rejection based on the '024 patent and Fairweather et al., the Office alleges that the motivation to combine Francis et al. and Fairweather can be found in Fairweather et al., which allegedly teach that the pTet18 tetanus toxin was easier to obtain than a protein allegedly containing only fragment C of the tetanus toxin (i.e., pTet11). (*Id.* at 12.)

For the same reasons that there is no motivation to combine the teachings of the '024 patent and Fairweather et al., there is similarly no motivation to combine the teachings of Fairweather et al. with those of Francis et al. Thus, any alleged motivation to combine these references based on the '024 patent is inappropriate hindsight reconstruction based solely on the teachings of the present specification. *See In re Dow Chemical Co.*, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988).

(b) Claims 36 and 37

In addition to the reasons discussed above, applicants respectfully assert that Francis et al., in view of Fairweather et al., does not render claims 36 and 37 obvious for the additional reasons discussed below.

Claim 36 depends from claims 1 and 31 and recites that the fusion protein comprises an amino acid sequence comprising SEQ ID NO:16. Neither Francis et al. nor Fairweather et al. disclose an amino acid sequence comprising SEQ ID NO:16. Thus, the cited references do not teach or suggest every element of claim 36.

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Claim 37 depends from claims 1 and 31 and recites that the non-toxic, proteolytic fragment of tetanus toxin consists of a fragment C and the 11 amino acid residues of fragment B that immediately precede the amino terminus of fragment C. Neither Francis et al. nor Fairweather et al. disclose a tetanus toxin consisting of a fragment C and the 11 amino acid residues of fragment B that immediately precede the amino terminus of fragment C. In addition, neither Francis et al. nor Fairweather et al. suggest modifying either the pTet18 tetanus toxin construct of Fairweather et al. or the TTC fragment of Francis et al. to obtain a tetanus toxin consisting of a fragment C and the 11 amino acid residues of fragment B that immediately precede the amino terminus of fragment C, as claimed. *See University of Washington*, 2002 WL 1305996 at *17. Thus, the cited references do not teach or suggest every element of claim 37.

Accordingly, for these additional reasons, applicants respectfully request that this 35 U.S.C. § 103 rejection be withdrawn from claims 36 and 37.

(c) Remaining Claims

The Office also made the following rejections under 35 U.S.C. § 103 based on Francis et al.:

1. Claims 9 and 10 were rejected as allegedly obvious over Francis et al. in view of Fairweather et al., as applied to claims 1-8, 11, and 31, and further in view of Fishman. (Paper No. 13, pp. 12-13, ¶ 14).

2. Claims 6-8, 11, 31, 33, 35, and 36 were rejected as allegedly obvious over Francis et al. in view of Fairweather et al., as applied to claims 1-8, and further in view of U.S. Patent No. 6,159,948. (Paper No. 13, p. 14, ¶ 15).

3. Claims 6-8, 11, 31, and 33-36 were rejected as allegedly obvious over

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Francis et al. in view of Fairweather et al., as applied to claims 6-8, and further in view of Liston et al. (Paper No. 13, p. 15, ¶ 16).

Applicants respectfully traverse each of these rejections.

As discussed above, Francis et al. do not teach every element of applicants' claimed invention. Specifically, Francis et al. do not teach *in vivo* transynaptic transport of a fusion protein containing a tetanus toxin fragment. The remaining references relied on by the Office, Fairweather et al., Fishman et al.,[5] U.S. Patent No. 6,159,948, and Liston et al. fail to remedy the deficiencies of the '024 patent. None of these secondary references teaches or suggests the *in vivo* transynaptic transport of a fusion protein containing a tetanus toxin fragment. In addition, as discussed above, there is no motivation to combine Francis et al. with Fairweather et al. Accordingly, applicants respectfully request withdrawal of these 35 U.S.C. § 103 rejections.

CONCLUSION

In view of the foregoing remarks, applicants respectfully request reconsideration and reexamination of this application and timely allowance of the pending claims.

If there are any fees due in connection with the filing of this paper not already accounted for, please charge the fees to our Deposit Account No. 06-0916.

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[5] The Office asserts that Fishman et al. teach *in vivo* transynaptic transport of a fusion protein, because Fishman et al. state that "[l]inkage with [tetanus toxin C fragment] also **may** enhance the stability of a chosen protein within the CNS as well as promote its spread by transsynaptic transport." (Paper No. 13, p. 13 (emphasis added)). This statement does not demonstrate *in vivo* transynaptic transport of a tetanus toxin fragment C fusion protein. It is mere speculation. Furthermore, as discussed in the specification, while others have shown that the tetanus toxin fragment C can undergo retrograde transport, they have not demonstrated that it can undergo *in vivo* transynaptic transport. (Specification, pp. 2-4).

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Respectfully submitted,

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Dated: December 17, 2002

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Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
*1 BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON (5,302,529), JUNIOR PARTY
v.
ELI LILLY & CO. (09/185,663), SENIOR PARTY
Interference No. 104,733
Filed: June 11, 2002

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Before SCHAFER, TORCZON, and TIERNEY

Administrative Patent Judges

Tierney

Administrative Patent Judge

JUDGMENT

(PURSUANT TO 37 CFR § 1.640)

This interference is before a motions panel for a decision on preliminary motions. Oral argument took place on April 3, 2002. No transcript of the oral argument is available as the parties did not provide a court reporter.

I. Summary of the Decision

The issues presented in this interference are straightforward. University of Washington ("UW") has requested a judgment of no interference-in-fact. As permitted by the rules, Lilly has requested that, prior to determining the question of no interference-in-fact, we designate an additional UW claim as corresponding to the count.

The Federal Circuit has stated that no interference-in-fact means that there is no interfering subject matter. Thus, no interference-in-fact means that the parties are claiming different patentable inventions, an example of which occurs when the claimed subject matter of a party's patent would not impede the granting of an applicant's claims. As such, the issues raised by the parties are simply a question of whether or not UW's patent claims would prevent the issuance of Lilly's claims.

There is a rebuttable presumption that each claim designated as corresponding to a count defines the same patentable invention as all other claims designated as corresponding to the count. Indeed, 37 CFR § 1.601(j) states that:

An "interference-in-fact" exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

Accordingly, in analyzing the question of no interference-in-fact, we compare a party's corresponding claims to an opponent's corresponding claims. Specifically, we presume that the subject matter of a party's corresponding claims are "prior art" to an opponent's corresponding claims in order to determine whether or not the parties invented the same patentable invention. Where a party's corresponding claims are separately patentable from an opponent's corresponding claims, a judgment of no interference-in-fact is appropriate.

Presently, UW is involved in this interference on the basis of UW claim 3, a "species" claim. Lilly has requested that UW claim 1, a "genus" claim, be added to the interference as corresponding to Count 1, the sole count in the interference.

*2 UW's corresponding "species" claim does not anticipate or render obvious any of Lilly's corresponding claims. Nor would UW's "genus" claim, should it correspond, anticipate or render obvious any of Lilly's corresponding claims. Accordingly, UW's species and genus claims are not an impediment to granting Lilly's corresponding claims.As such, we grant UW's motion for no interference-in-fact.

The parties have entered into a vigorous dispute as to the relative merits of the Board's precedential decision in Winter v. Fujita, 53 USPQ2d 1234 (Bd. Pat. App. & Int. 1999). As the questions presented in this interference do not require our reliance on any issue resolved in Winter, we need not address the parties' comments regarding that decision.

II. The Technology in Question

Generally, the technology involved in this interference relates to cDNA that codes for a polypeptide ("protein") having human protein C activity. Protein C is a zymogen, or inactive precursor, of a plasma serine protease, activated protein C

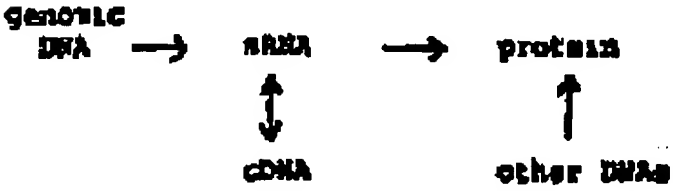
("APC"). Specifically, protein C is formed as a single-chain polypeptide that undergoes processing to form a two-chain molecule having a heavy chain and a light chain that are connected via disulfide bonds. This two- chain intermediate is converted to APC by cleaving a 12-residue peptide from the heavy chain. APC plays a critical role in the regulation of blood coagulation as it represents a physiological mechanism for blood anticoagulation. [FN1]

To understand the nature of cDNA it is necessary to understand the function of DNA. DNA ("deoxyribonucleic acid") is the blueprint of an organisms genetic makeup as it is the primary genetic material. In an organism, a portion of DNA, a gene, may undergo transcription to form mRNA (messenger ribonucleic acid). The mRNA in turn, may then be translated to form a polypeptide, e.g., an enzyme or a structural protein.

DNA is the term used to represent the complex macromolecules made up of nucleotide units. A nucleotide unit is characterized by a specific combination of a base, a sugar and a phosphoric acid residue. There are four different nucleotide units in DNA: adenine ("A"), guanine ("G"), cytosine ("C") and thymine ("T").

As explained in In re Deuel:

> A sequential grouping of three such nucleotides (a "codon") codes for one amino acid. A DNA's sequence of codons thus determines the sequence of amino acids assembled during protein synthesis. Since there are 64 possible codons, but only 20 natural amino acids, most amino acids are coded for by more than one codon. This is referred to as the "redundancy" or "degeneracy" of the genetic code.
>
> DNA functions as a blueprint of an organism's genetic information. It is the major component of genes, which are located on chromosomes in the cell nucleus. Only a small part of chromosomal DNA encodes functional proteins.
>
> *3 Messenger ribonucleic acid ("mRNA") is a similar molecule that is made or transcribed from DNA as part of the process of protein synthesis. Complementary DNA ("cDNA") is a complementary copy ("clone") of mRNA, made in the laboratory by reverse transcription of mRNA. Like mRNA, cDNA contains only the protein-encoding regions of DNA. Thus, once a cDNA's nucleotide sequence is known, the amino acid sequence of the protein for which it codes may be predicted using the genetic code relationship between codons and amino acids. The reverse is not true, however, due to the degeneracy of the code. Many other DNAs may code for a particular protein. The functional relationships between DNA, mRNA, cDNA, and a protein may conveniently be expressed as follows:



In re Deuel, 51 F.3d 1552, 1554, 34 USPQ2d 1210, 1211 (Fed. Cir. 1995).

III. Findings of Fact

1. Real Parties in Interest

a. Junior Party

F1. University of Washington ("UW") is the owner of the entire right, title and interest in the involved U.S. Patent No. 5,302,529 ("'529"). Zymogenetics, Inc. is the exclusive licensee of the '529 patent. (Paper No. 11, Notice as to Real Parties In Interest, p. 2).

b. Senior Party

F2. Eli Lilly & Co. ("Lilly") is the real party in interest in the involved U.S. Reissue Patent Application 09/185,663. (Paper No. 5, Eli Lilly & Co. Identification of Real Party in Interest, p. 2).

2. Accorded Priority Benefit

a. Junior Party

F3. UW's involved U.S. Patent No. 5,302,529 issued on April 12, 1994, based upon U.S. Application No. 07/512,961, filed April 23, 1990. Solely for the purposes of priority, UW '529 has been accorded benefit of the filing date of:
U.S. Patent No. 4,968,626, issued November 6, 1990, based upon U.S. Application 06/766,109, filed August 15, 1985.
(Notice Declaring Interference, Paper No. 1, p. 3).

b. Senior Party

F4. Lilly's involved '663 reissue application is based upon U.S. Patent No. 4,775,624, which issued on October 4, 1988 from U.S. Application 06/699,967, filed February 8, 1985. (Notice Declaring Interference, Paper No. 1, p. 3).

3. The Count and Claim Correspondence

F5. Count 1, the sole count in the interference, is claim 3 of UW's U.S. Patent No. 5,302,529.

UW '529 claim 3 reads as follows:

3. The plasmid or transfer vector of claim 1, comprising the cDNA sequence of FIG. 3, from bp 127 to bp 1383.

F6. The claims of the parties are as follows:
*4 UW: 1-4
Lilly: 1-82 and 84-90

The claims of the parties that have been designated as corresponding to Count 1 are:

UW: 3

Lilly: 1-82 and 84-90

The claims of the parties that were not designated as corresponding to Count 1 are:

UW: 1, 2 and 4

Lilly: None

(Notice Declaring Interference, Paper No. 1, p. 4).

4. Relevant Facts Admitted By Lilly

a. Differences between the cDNA Sequence of UW Claim 3 and Lilly's Claimed Sequences

Lilly has admitted, among other things, the following material facts presented by UW.

F7. The human protein C cDNA sequence of UW claim 3, from bp 127 to bp 1383 of Foster's Fig. 3, encodes a protein of 419 amino acids, which is a precursor of protein C. (UW Preliminary Motion 1, Paper No. 17, p. 2, ¶ 4; Lilly Opposition 1, Paper No. 27, p. 2, ¶ 4, admitting first sentence of UW fact 4.)

F8. Comparing the sequence of UW Fig. 3, bp 127 to bp 1383, with the pertinent portions of the cDNA sequence of Lilly claim 1, two nucleotide differences are revealed in the coding region:

1) UW Fig. 3, nucleotide 423 (third position of codon 99) is thymine ("T"), whereas Lilly's is guanine ("G").

2). UW Fig. 3, nucleotide 768, (third position of codon 214) is cytosine ("C"), whereas Lilly's is thymine ("T").

(Paper No. 17, p. 3, ¶ 6; Paper No. 27, p. 3, admitting UW facts 6-16.) Both Lilly and UW's cDNA sequences are said to encode for human protein C. (Paper No. 27, additional facts ¶ ¶ 4, 6 and 7).

F9. The nucleotide variations between UW's Fig. 3 cDNA sequence and the sequence of Lilly claim 1 may be a DNA polymorphism. A polymorphism is defined as one of two different but normal nucleotide sequences existing at a particular site in DNA. The polymorphism may exist in the same individual, e.g., a heterozygous individual or among different individuals, and may encode the same or a different amino acid sequence. (Paper No. 17, pages 2-3, ¶ 7; Paper No. 27, p. 3, admitting UW facts 6-16.)

F10. According to several of Lilly's named inventors the variations between Lilly's sequence and UW's "may represent a true genetic variant." (Paper No. 17, page 4, ¶ 8; Paper No. 27, p. 3, admitting UW facts 6-16.)

F11. In seeking to provoke an interference with UW's '529patent, Lilly

represented to the reissue application examiner that:

... it is very likely that the actual Foster [UW] sequence is identical to the corresponding Bang [Lilly] sequence. Indeed, the sequence deposited by Foster in GenBank is identical to the corresponding sequence in claim 1 of the Bang application.

Lilly also informed the examiner that:

The Differences Between the Bang and Foster Sequences are Probably Foster Mistakes

As the Patent Office has recently recognized, it is well known that sequencing errors are a common problem in molecular biology. [omitted footnote] Evidence supporting the conclusion that the differences between the Bang and Foster sequences are due to sequencing errors by Foster may be found within the Foster patents themselves: the protein C DNA sequences shown in Figure 2 of Foster contains only one of the base differences: that at position 99. Further evidence may be found in the publications of Foster. Specifically, Foster published articles in the Proceedings of the National Academy of Sciences that showed DNA sequences matching both Patent Figure 3 (two base differences) and Figure 2 (one base difference). [omitted footnote] Later, Foster made a deposit of their protein C DNA sequence in GenBank; this deposited sequence is identical to the sequence of the Bang application.

* * *

***5** Applicants submit that this evidence, when viewed as a whole, clearly supports the conclusion that the two nucleotide differences in the Foster sequence are due to sequencing errors, and not due to true differences in cDNA sequence. (Paper No. 17, pages 6-8, ¶ 13, bold emphasis added; Paper No. 27, p. 3, admitting UW facts 6-16.)

F12. GenBank is a publicly accessible database of nucleic acid sequences. According to a review article published in 1985, it was GenBank's practice during the 1980's to gather nucleic acid sequences for their database from published scientific literature. (Paper No. 17, p. 8, ¶ 14; Paper No. 27, p. 3, admitting UW facts 6-16.)

F13. Lilly advised the reissue application examiner that Lilly's sequence was deposited with GenBank under Accession Number X02750. Specifically, Lilly informed the examiner that there is "absolute similarity" between the sequence in Lilly's '663 reissue application and the GenBank X02750 sequence. (Paper No. 17, p. 8, ¶ 16; Paper No. 27, p. 3, admitting UW facts 6-16.)(Paper No. 17, p. 8, ¶ 16; Paper No. 27, p. 3, admitting UW facts 6-16.)

F14. Lilly informed the reissue application examiner that GenBank Sequence NM_000312 was UW's protein C DNA sequence. (Paper No. 17, p. 9, ¶ 17; Paper No. 27, p. 3, fact 17, stating that Lilly had a good faith belief that its statements regarding the origins of UW's sequences were true and if Lilly was in error, the error was inadvertent.)

F15. Lilly's reissue prosecution statements that Foster deposited the NM_ 0003212

are mistaken. The record demonstates that the NM_0003212 sequence was derived from Lilly's X02750 sequence. (Paper No. 17, p. 10, ¶ 20; Paper No. 27, p. 3, admitting UW facts 18-21).

b. Coding Sequence Unpredictability

F16. Even if one predicted the existence of at least one DNA polymorphism in a gene, one could not predict where in the coding sequence the difference(s) would occur, how many differences would occur, or what the differences would be. As such, provided with the coding sequence of a single gene, one of ordinary skill in the art could not predict with accuracy the number or location of DNA differences between the genes of different people encoding the same protein. (Paper No. 17, p. 5, ¶ 10; Paper No. 27, p. 3, admitting UW facts 6-16.)

F17. The two codon differences between UW's claim 3 sequence and Lilly's claim 1 sequence could not have been predicted in advance based on knowledge of either Lilly's nucleotide sequence or Lilly's amino acid sequences. (Paper No. 17, p. 5, ¶ 11; Paper No. 27, p. 3, admitting UW facts 6-16.)

F18. One of ordinary skill in the art could not have predicted the particular DNA sequence of UW claim 3 based on the amino acid sequence of human protein C light chain, such as that recited in Lilly claim 81, or a particular DNA encoding that amino acid sequence, such as that provided in Lilly claim 82. (Paper No. 17, p. 11, ¶ 21; Paper No. 27, p. 3, admitting UW facts 18-21).

IV. Opinion

***6** An Administrative Patent Judge ("APJ") declared this interference based, in part, on statements made during the examination of Lilly's reissue application. UW claim 3 is directed to a plasmid or transfer vector comprising a string of base pairs identified in the cDNA sequence of UW Figure 3. During the prosecution of Lilly's reissue application, Lilly represented to the examiner that Foster ("UW") had deposited a nucleotide sequence encoding protein C that was identical to the corresponding sequence of Lilly's claim 1. (UW Preliminary Motion 1, Paper No. 17, pages 6-8, ¶ 13, Lilly Opposition 1, Paper No. 27, p. 3, admitted facts 6-16). According to Lilly:

> Applicants submit that this evidence, when viewed as a whole, clearly supports a conclusion that the two nucleotide differences in the Foster sequence [UW Figure 3] are due to sequencing errors, and not due to true differences in cDNA sequence. Id.

When the interference was declared, the Office was unaware that the purported "Foster sequence," Accession No. NM_00312 was Lilly's own sequence. (Paper No. 17, p. 9, ¶ ¶ 17, 20; Paper No. 27, p. 3, Lilly stated that it had a good faith belief that its statements were true and that any error was "inadvertent."). In light of the evidence provided by UW, we find that Lilly's statements regarding the origin of the deposited sequence were incorrect and that the claimed UW species and Lilly species are apparently genetic variants. (See, Paper No. 17, p. 4, ¶ 8, Paper No. 27, p. 3, admitting facts 6-16).

UW has filed a preliminary motion seeking a judgment of no interference-in- fact based on the differences between the sequence of UW claim 3 and the sequences recited in Lilly's claims. (UW Preliminary Motion 1, Paper No. 17, p. 1). In response to UW's motion, Lilly filed a preliminary motion requesting that the interfering subject matter be redefined to have UW claim 1 designated as corresponding to Count 1. (Lilly Preliminary Motion 1, Paper No. 27, p. 1). [FN2]

1. What is Required for a Determination of "No Interference-In-Fact"

Both UW and Lilly agree that there is an interference-in-fact when two parties are claiming the same patentable subject matter. The parties, however, disagree as to the test for determining whether the parties claims define the same patentable subject matter.

While 35 U.S.C. § 135(a) sets forth the requirements for declaring an interference, the statute fails to explicitly state the requirements for determining whether there is no interference-in-fact once an interference has been declared. To aid us in our understanding, we look to the United States Patent & Trademark Office's ("USPTO") rules regarding no interference-in-fact. Yet, as the comments to the rules specifically state that USPTO would continue to follow the decisions rendered in Case v. CPC International, Inc., [FN3] Aelony v. Arni, [FN4] and Nitz v. Ehrenreich, [FN5] we review these decisions prior to our review of the USPTO rules. Notice of Final Rules, 49 Fed. Reg. 48416, 48,421 (Dec. 12, 1984).

A. The Opinions of the Federal Circuit and the Court of Customs and Patent Appeals ("CCPA")

1. Nitz v. Ehrenreich

*7 Nitz involved an appeal from the Board of Patent Interferences [FN6] awarding priority of invention to Ehrenreich. Specifically, the Board awarded priority of invention as to two counts, counts 1 and 2, to Ehrenreich. Nitz appealed the decision arguing, among other things, that there was no interference-in-fact as to either count.

The interference was provoked when senior party Ehrenreich copied, in modified form, claims 3 and 13 of Nitz's U.S. Patent No. 3,552,533. The subject matter of the two copied claims involved carbonized articles having a modifying agent to increase the coefficient of friction of carbon. Of note, count 1 required up to about 48 percent by weight of a friction modifier and count 2 required carbonized layers of filamentary materials.

During the Board proceeding, Nitz argued that the counts did not define common subject matter that was claimed by both parties. In reviewing Nitz's arguments with respect to count 1, the Board recommended to the Commissioner that the interference be dissolved. Specifically, the Board viewed Nitz's limitation of up to 12 weight percent of a friction modifier as defining a patentably distinct invention from that of count 1, which required up to about 48 weight percent of the friction

modifier. The Commissioner, however, disapproved of the recommendation as the Commissioner was of the opinion that the amount of the modifier was not a critical limitation and that there was no basis for Nitz and Ehrenreich's claims to exist in separate patents. As to count 2, the Board determined that the count's failure to recite the term "woundup," as found in Nitz's claimed carbonized layers, was not a patentable distinction.

Additionally, Nitz raised the issue of Ehrenreich's "right to make count 1." As to this issue, the Board determined that Ehrenreich's disclosure was sufficient to support the limitations of the count. Having decided the issues of no interference-in-fact and right to make the counts, the Board awarded priority on both counts to Ehrenreich. Nitz appealed.

In reviewing the question of interference-in-fact and the court's jurisdiction to consider that issue, the CCPA stated:

The existence of common subject matter defined by the interference count is a prerequisite for an award of priority, i.e., the existence or nonexistence of interfering subject matter goes to the very foundation on which an interference rests. Determination of the presence or absence of interfering subject matter is "logically related" to the jurisdiction-conferring issue of priority because that determination necessarily precedes a priority award.
537 F.2d at 543, 190 USPQ at 416.

As to the question of no interference-in-fact, the CCPA compared the disclosure and claims of Nitz with the count and the disclosure of Ehrenreich. According to the CCPA:

***8** In the case before us the materiality of the questioned limitation and its variation must be determined in a two-step process wherein the first inquiry is [1] whether the variation changes a material aspect of the patentee's invention (here, whether the maximum amount of friction modifier of "up to 12 percent by weight" is a material limitation) and, if that inquiry be decided in the affirmative, the second inquiry is [2] whether the variation is itself a material variation (here, whether "up to 48% by weight" results in the counts being drawn to a different invention).
Id. at 544, 190 USPQ at 417.

Conducting the two-step inquiry, the CCPA focused on Nitz's description that at least 80 weight percent carbon was a critical feature of the invention and the limitation that the modifier was present in an amount "up to 12% by weight." Furthermore, the CCPA focused on Ehrenreich's disclosure of using up to 48% by weight modifier, which would allow fora maximum of 52% by weight carbon. Id. at 544, 190 USPQ at 417-18.

The CCPA determined that Nitz's claim recitation of "up to 12% by weight" of a modifier was a material limitation due to the critical nature of having at least 80% carbon. The CCPA then determined that the count language "up to about 48% by weight" of the modifier was a material variation from Nitz's claimed invention. As such, the CCPA concluded that no interference-in-fact existed with respect to count 1. Id. at 545, 190 USPQ at 418.

As to count 2, the only issue on appeal was the materiality of Nitz's recitation that the carbonized layers of filamentary materials were "woundup" layers. The CCPA, however, determined that the structure of woundup layers was known in the

prior art and that the limitation was not necessary for the patentability of Nitz's claim. As such, the CCPA determined that Nitz's "woundup" limitation was not a material limitation of Nitz's claim and that an interference-in-fact existed with respect to count 2.

Nitz is consistent with the principle that there is no interference-in- fact when two parties are claiming "materially" different inventions. Further, Nitz is consistent with the principle that, for purposes of no interference- in-fact, claims of different scope can be separate patentable inventions even where one party's claim is literally encompassed by a second party's claim. Specifically, the CCPA found that Nitz's claimed "up to 12% by weight" modifier was a materially different invention from Ehrenreich's claimed "up to 48% by weight" modifier even though Nitz's claimed amount of modifier was literally encompassed by Ehrenreich's claimed amount of modifier.

2. Aelony v. Arni

***9** Aelony concerned an appeal from a decision of the Board awarding priority of invention to Arni, the senior party. The subject matter of the interference was a method for purifying malononitrile. In particular, both parties treated an impure malononitrile with a conjugated diene in a Diels- Alder reaction to aid in the removal of impurities. Of note, Aelony taught the use of cyclopentadiene, a conjugated diene. In contrast, Arni did not specifically describe or claim cyclopentadiene as a suitable Diels-Alder reaction component for the removal of impurities. Rather, Arni specifically described eight other materials having conjugated double bonds as suitable for undergoing a Diels-Alder reaction for the removal of impurities. Aelony v. Arni, 547 F.2d 566, 567, 192 USPQ 486, 487 (CCPA 1977).

Before the Board, neither Aelony nor Arni took testimony. Rather, Aelony argued that there was no interference-in-fact between the parties. Specifically, Aelony argued that, for the purification method in dispute, cyclopentadiene was patentably distinct from the eight materials described by Arni. Id. at 568, 192 USPQ at 488. The Board did not agree. According to the Board, both parties carried out substantially the same process. Moreover, the Board found that Aelony's patentable distinctiveness argument was unsupported by the evidence. As such, the Board rejected Aelony's no interference-in-fact argument and awarded priority to senior party Arni. Id. at 568, 192 USPQ at 488.

In reviewing the merits of Aelony's appeal, the CCPA specifically rejected Aelony's argument that there was no interference-in-fact. The CCPA agreed with the Board "that the test of interference-in-fact is not whether two sets of claims overlap, but whether they are patentably distinct from each other." Id. at 570, 192 USPQ at 490 (bold emphasis added). According to the CCPA, the law contemplates that "where different inventive entities are concerned - that onlyone patent should issue for inventions which are either identical to or not patentably distinct from each other." Id. (bold emphasis added). The CCPA went on to state that "[m]oreover, we believe that there is ample precedent from this court for framing the test of interference in fact in terms of whether two sets of claims are patentably distinct from each other." Id. (bold emphasis added).

On the facts presented, the CCPA determined that "both parties are claiming the same inventive concept" and rejected Aelony's argument that there was no interference-in-fact. Id. (bold emphasis added). In particular, the CCPA noted that both parties carried out the same process in which a conjugated diene material reacted with impurities according to the Diels-Alder reaction. Further, there was no dispute that the cyclopentadiene of Aelony and the eight conjugated dienes of Arni were all common Diels-Alder dienes. Id.

***10** The decision in Aelony denied a motion for no interference-in-fact where two parties were claiming patentably indistinct inventions. Specifically, in deciding the question of no interference-in-fact, the CCPA focused its attention on whether or not the parties claims were patentably distinct from each other. Where the claims of the parties are not patentably distinct from each other, the parties are claiming the same inventive concept and it is understood that only one patent should issue.

3. Case v. CPC International, Inc.

Case involved an appeal from a decision of a district court in a civil action under 35 USC § 146 upholding the award of priority to CPC International, Inc., ("CPC") in an interference proceeding in the USPTO. The subject matter in the interference was directed to polyether polyols that consisted essentially of oxyalkylated polyalcohols and oxyalkylated polysaccharides. Case v. CPC Int'l, Inc., 730 F.2d 745, 747, 221 USPQ 196, 198 (Fed. Cir. 1984).

The interference was provoked by CPC. To provoke the interference, CPC copied Case's patented claims. Of note, Case's patented claims specified that an oxyalkylated polyalcohol was present in an amount of 10 to 95% by weight and that an oxyalkylated polysaccharide was employed in an amount of 5 to 95% by weight. During examination, CPC's claims were rejected as lacking sufficient written descriptive support under 35 U.S.C. § 112, 1st paragraph, for the copied weight limitations. The examiner, however, advised CPC to submit claims directed to "a polyether polyol which is the reaction product of starch and the various disclosed derivatives thereof with glycerin and propylene oxide." Id. In response to the examiner's rejection of the copied claims, CPC canceled the copied claims and submitted new claims that complied with the examiner's suggestion. Id. The newly added CPC claims, however, did not recite a particular weight limitation for the two oxyalkylated components. Moreover, when the interference was declared, the counts did not recite the weight limitations found in Case's patented claims.

Case presented numerous arguments challenging both the district court and the Board's award of priority to CPC. Of interest, Case argued that no interference-in-fact existed between Case's claims and CPC's. According to Case, the question of no interference-in-fact turned on whether or not the weight limitations present in Case's claims, but not CPC's claims, were material. The Federal Circuit agreed with this analysis. [FN7] Id. at 750, 221 USPQ at 200.

***11** According to the Federal Circuit, the question of materiality of the omitted limitations was one of fact. Id. The Court noted that both the district court and the Board had determined that the omitted weight limitations were not material as the range of proportions was quite broad and that Case's prosecution history

demonstrated that the omitted limitations were not pertinent to patentability.

Additionally, Case argued that there was no interference-in-fact as the counts were unpatentable. Having reviewed Case's arguments, the Federal Circuit stated that:

No interference in fact means that there is no interfering subject matter, that Case's patent is no impediment to granting CPC the claims of its application. It was Case's burden to prove that CPC claims a different invention from his own. Case cannot carry that burden with argument that the counts are unpatentable.

Id. (emphasis added). The Federal Circuit also stated that "[i]n sum, since the Case patent and the CPC application contain interfering subject matter, an interference proceeding was appropriate." Id. at 752, 221 USPQ at 202. The Court then went on to uphold the decision awarding priority of invention to CPC based upon its earlier application. Id.

As apparent from the decision in Case, the question of no interference-in- fact turns on whether or not the parties claims are "materially" different. The question of "material" differences being one of fact. Further, Case specifies that no interference-in-fact exists where one party's patent does not impede the grant of another party's claims.

4. Summary of the CCPA and Federal Circuit Opinions on the Question of No Interference-in-Fact

An interference in fact involves interfering subject matter. As shown by the above decisions, there is no interfering subject matter, and thus, no interference-in-fact when the parties are claiming different patentable inventions. For example, there is no interference-in-fact when it is demonstrated that a party's claims are no impediment to the granting of an opponents claims. Case, 730 F.2d at 750, 221 USPQ at 200.

The cases analyzed above, Nitz, Aelony and Case and our interpretations thereof are all consistent with the no interference-in-fact decisions in Almasi v. Strauss, 589 F.2d 523, 200 USPQ 511 (CCPA 1979), and Brailsford v. Lavet, 318 F.2d 942, 138 USPQ 28 (CCPA 1963) as well as the interference-in-fact decision in McCabe v. Cramblet, 65 F.2d 459, 18 USPQ 71 (CCPA 1933).

B. The USPTO Rules and the Comments to the Rules Provide that No Interference- in-Fact Exists for Patentably Distinct Inventions

***12** The interference rules were revised in 1984 to implement the interference provisions of the Patent Law Amendments Act of 1984 (Public Law 98-622). Notice of Final Rule, Patent Interference Proceedings, 49 Fed. Reg. 48416 (Dec. 12, 1984). As part of the rule revision, the Commissioner (now Director) promulgated several rules regarding the existence of an interference- in-fact. For example, the Commissioner promulgated 37 CFR Section 1.601(j)(definition of an interference-in-fact), Section 1.601(n)(definition of same and separate patentable inventions) and Section 1.633(b), which authorized parties to file preliminary motions for judgment on the ground that there is no interference-in-fact.

In their present form, Rules 601(j), 601(n) and 633(b) read as follows:

Rule 601(j) An interference-in-fact exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.

Rule 601(n) Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

Rule 633(b) A motion for judgment on the ground that there is no interference-in-fact. A motion under this paragraph is proper only if the interference involves a design application or patent or a plant application or patent or no claim of a party which corresponds to a count is identical to any claim of an opponent which corresponds to that count. See § § 1.637(a). When claims of different parties are presented in "means plus function" format, it may be possible for the claims of the different parties not to define the same patentable invention even though the claims contain the same literal wording.

***13** Rules 601(j) and (n): 49 FR 48416, Dec. 12, 1984, effective Feb. 11, 1985; 50 FR 23123, May 31, 1985; revised, 60 FR 14488, Mar. 17, 1995; Rule 633(b): 49 FR 48416, Dec. 12, 1984, added effective Feb. 11, 1985; 50 FR 23124, May 31, 1985; revised, 60 FR 14488, Mar. 17, 1995, effective Apr. 21, 1995.

While the rules explicitly define when an interference-in-fact exists, the rules do not explicitly define "no" interference-in-fact. The comments to the rules, however, provide that the USPTO will continue to follow the decisions rendered in Nitz, Aelony and Case. Notice of Final Rules, 49 Fed. Reg. 48416, 48421 (Dec. 12, 1984). As provided above, these three decisions demonstrate that the test for no interference-in-fact is grounded in patentable distinctness. Nitz, 537 F.2d at 545, 190 USPQ at 418; Aelony, 547 F.2d at 570, 192 USPQ at 490; Case, 730 F.2d at 750, 221 USPQ at 200. As such, a party may demonstrate that no interference-in-fact exists between two parties by proving that a first party's claim(s) are patentably distinct from the second party's claim(s).

The test for patentable distinctness is set forth in Rule 601(n), which states that an invention "A" is a separately patentable invention, i.e. patentably distinct, with respect to invention "B" when invention "A" is novel and non-obvious in view of invention "B" assuming invention "B" is prior art with respect to invention "A". For example, party A's claims are patentably distinct, i.e., separately patentable, when the party A's claims are no impediment to the granting of the opponents claims. See, e.g., Nitz, 537 F.2d at 544-45, 190 USPQ at 417-18 (No interference-in-fact where "up to 48%" modifier did not interfere with "up to

12%" modifier); Case, 730 F.2d at 750, 221 USPQ at 200 ("No interference in fact means that there is no interfering subject matter, that Case's patent is no impediment to granting CPC the claims of its application.").

C. Lilly's Species Anticipates Dominating Genus Theory of Interference-in-Fact Lacks Merit

Lilly argues that for an interference in fact, the interference rules and comments require nothing more than a "species anticipates dominating genus" determination. Thus, according to Lilly, its claimed species is the "same patentable invention" as UW's claimed genus based on the fact that its species would anticipate UW's genus.

***14** Lilly states that the comments specifically inform the public that the test under Rule 601(n) for determining the "same" patentable invention could not be applied two ways, i.e. a party need only demonstrate "one-way" anticipation or obviousness for an interference-in-fact. Specifically, Lilly has argued that:

> The regulations of the PTO, 37 CFR § 1.601(n), having the force and effect of law, require nothing more than the "species anticipates dominating genus" determination to establish the existence of an interference-in-fact. Indeed, the official commentary issued by the PTO at the time the rules were adopted made clear that the test for the "same patentable invention" under 37 CFR § 1.601(n) could not be applied two ways. 49 FR 48416 at 48434 (Dec. 12, 1984). As stated by the PTO in the administrative history for the regulations, the "same patentable invention' [test] ... under § 1.601(n) ... [is] not intended to be 'applied in a mutuality sense."' [Footnote omitted].

(Lilly Preliminary Motion 1, Paper No. 22, p. 5, emphasis added). Additionally, responding to comments from UW, Lilly stated:

> In response to a specific question posed by one commentator in 1984 asking whether the PTO's proposed Rule 1.601(n) would involve a one-way or two-way patentability determination, the Office responded in unequivocal terms that a one-way test would be applied. Notice of Final Rules, 49 Fed. Reg. 48,416, 48,433 (1984). Six years later this rule was restated by the Board in Chiong v. Roland, 17 U.S.P.Q.2d 1541, 1544 (Bd. Pat. App. & Int. 1990)("As pointed out in the Notice, supra at 48433, the standard of patentability will not be applied on a 'mutual basis."')

(Lilly Reply 1, Paper No. 30, pages 8-9, emphasis added). This panel has reviewed the comments to the rules and finds no merit in Lilly's "species anticipates dominating genus" test.

Lilly has relied upon two specific comments to the rules. The comments may be found at pages 48,433-48,434 of the Notice of Final Rules, 49 Fed. Reg. 48,416 (Dec. 12, 1984). Provided below are the full paragraphs ((1) & (2)) from which Lilly's quoted material is derived:

> (1) With respect to paragraph (1) of the comment, the standard of patentability will not be applied "on a mutual basis." Thus, if a species is patentable over a genus, the species is a "separate patentable invention" from the genus. Compare In re Taub, 348 F.2d 556, 146 USPQ 384 (CCPA 1965) (fluorine species might be patentable over genus of Markush group of hydrogen and halogen). A first count to a genus and a second count to a species which is patentable over the genus may properly appear in an interference. See e.g., Example 4. The comment suggests that

if "such mutuality is not applied * * * then a number of irreconcilable anomalies * * * will be manifest." The urged "irreconcilable anomalies" are not readily apparent to the PTO.
*15 (Fed. Reg., p. 48433, underline emphasis added denotes Lilly's cited commentary, bold emphasis added to highlight application of Rule 601(n) for genus/species situations).

(2) Analysis of Commentator's Example A. Example A does not describe any practice under these rules, because "same patentable invention" and "separate patentable invention" under § 1.601(n) are not intended to be "applied in a mutuality sense." Where a first count is to a genus and a second count is to a species within the scope of the genus, there may be two counts if the species is separately patentable from the genus. The species is "invention A" referred to in § 1.601(n); the genus is "invention B" referred to in § 1.601(n).
(Fed. Reg., p. 48434, underline emphasis added denotes Lilly's cited commentary, bold emphasis added to highlight application of Rule 601(n) for genus/species situations). [FN8]

The comments to the rules regarding the test for "same or separate patentable inventions" are highly relevant and material to the issues raised in this interference as they inform the public that a genus and a patentably distinct species are separate patentable inventions. If the rule were only applied in the manner suggested by Lilly, i.e., nothing more than species anticipates dominating genus, then the comments to the rule that a species that is patentable over a genus is a "separate patentable invention" from the genus would make no sense. Specifically, Lilly's argument would have us determine that the species and dominating genus defined both the same patentable invention and, at the same time, a separate patentable invention. Consistent with the precedential Federal Circuit and CCPA opinions mentioned above, the comments to rules explicitly provide that a patentably distinct species and a dominating genus are separately patentable inventions.

2. Lilly and UW's Corresponding Claims Are Separate Patentable Inventions As UW's Corresponding Claims Do Not Impede the Grant of Lilly's Corresponding Claims

The test for no interference-in-fact is whether or not the parties are claiming separately patentable inventions. In applying this test, we begin with a comparison of the parties' corresponding claims as there exists a rebuttable presumption that each claim designated to correspond to a count defines the same patentable invention as all other claims designated to correspond to the count. See, e.g., Orikasa v. Oonishi, 10 USPQ2d 1996, 2004 (Comm'r Pat. & Trademark 1989).

Count 1 is the sole count in interference. As declared, UW claim 3 and Lilly claims 1-82 and 84-90 correspond to Count 1. Additionally, Lilly has requested that UW claim 1 be designated as corresponding to Count 1. For purposes of determining if there is no interference-in-fact between the parties, we will assume that Lilly is correct in stating that UW claim 1 corresponds to Count 1. Accordingly, we compare UW claims 1 and 3 with Lilly's corresponding claims to determine whether the parties are claiming separately patentable inventions.

A. Anticipation and Obviousness

*16 A prima facie case of obviousness is established when the teachings of the prior art would have suggested the claimed subject matter to a person of ordinary skill in the art with a reasonable likelihood of success of achieving the suggested invention. In re Dow Chem., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Any motivation or suggestion to modify the prior art references must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed Cir. 1995); In re Gorman, 933 F.2d 982, 986-87, 18 USPQ2d 1885, 1888, (Fed. Cir. 1991).

A claim to a specific cDNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the various cDNA that have the potential to encode that protein. Cf., Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997) ("We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein."); In re Deuel, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995) ("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."); In re Bell, 991 F.2d 781, 787, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) ("It may be true that, knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one thus has the potential for obtaining that gene... Therefore, given the nearly infinite number of possibilities suggested by the prior art, and the failure of the cited prior art to suggest which of those possibilities is the human sequence, the claimed sequences would not have been obvious.").

Anticipation is the epitome of obviousness. Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983) (citing In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982)). Anticipation is established only if each and every element of a properly construed claim is found, either expressly or inherently described, in a prior art reference. PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624-1625 (Fed. Cir. 1996).

B. UW Claim 3 is Patentably Distinct from Lilly's Corresponding Claims

*17 UW claim 3 is directed to a plasmid or transfer vector that comprises the cDNA sequence depicted in UW Figure 3, from base pair 127 to base pair 1383. Lilly claim 1 corresponds to Count 1 and requires a constructed DNA compound that encodes a polypeptide with human protein C activity wherein the coding strand comprises several distinct cDNA species. Lilly claims 2-75, 77-80 and 84-88 all depend from Lilly claim 1 or require a DNA compound of Lilly claim 1. Of the remaining Lilly corresponding claims, Lilly claim 76 is directed towards several "intermediate" plasmids that lack the protein C cDNA, while Lilly claims 81 and 82 relate to recombinant DNA sequences that comprise the coding sequence for the active light chain of human protein C. Thus, as it is readily apparent that Lilly's intermediate plasmids are patentably distinct from UW claim 3, the proper comparison for patentable distinctness is between the cDNA species of UW claim 3 and the cDNA

species recited in Lilly claim 1 and Lilly claims 81 and 82. [FN9]

The sequence claimed in UW claim 3 is a cDNA sequence having at least 1257 base pairs, i.e., 419 codons (three base pairs to a codon), that encode a protein of 419 amino acids. For such a sequence, the odds of randomly changing a single codon are 1 in 419, changing any two codons at random is 1 in 175,142 (419 x 418), changing any three codons at random is 7,303,214 (419 x 418 x 417), etcetera. (See generally, Paper No. 17, pages 5-6, ¶ 11).

Comparing the sequence of UW claim 3 (UW Fig. 3, bp 127 to bp 1383) with the pertinent portions of the cDNA sequence of Lilly claim 1, two nucleotide differences are revealed in the coding region:

1) UW Fig. 3, nucleotide 423 (third position of codon 99) is thymine ("T"), whereas Lilly's is guanine ("G").

2). UW Fig. 3, nucleotide 768, (third position of codon 214) is cytosine ("C"), whereas Lilly's is thymine ("T").

(Paper No. 17, p. 3, ¶ 6; Paper No. 27, p. 3, admitting UW facts 6-16.). The parties agree that:

The particular differences in the nucleotide sequences that occur between the sequences of Foster [UW] claim 3 and Bang [Lilly] claim 1 within two different codons could not have been predicted in advance based on knowledge of either Bang's nucleotide or amino acid sequences alone.

(Paper No. 17, p. 5, ¶ 11; Paper No. 27, p. 3, admitting UW facts 6-16.).

When there is a specific, structurally related prior art compound, the question of obviousness is whether the prior art suggested the specific modifications necessary to achieve the claimed compound. In re Deuel, 51 F.3d at 1557-58, 34 USPQ2d at 1214. On the record presented, there is insufficient evidence that Lilly's claimed sequence, taken in combination with the prior art, would have suggested the specific modifications to nucleotide 423 and nucleotide 768 such that one skilled in the art would arrive at the cDNA sequence described by UW claim 3. Additionally, there is insufficient evidence that one skilled in the art presented with the amino acid sequence of human protein C would have been guided to form the specific cDNA sequence recited in UW claim 3. In re Deuel, 51 F.3d at 1559, 34 USPQ2d at 1215-16 (Due to enormous number of DNA molecules encoding for the protein, disclosure of amino acid sequence did not render particular DNA molecules encoding the protein obvious). We conclude that Lilly claim 1 and UW claim 3 are patentably distinct as Lilly claim 1 does not render UW claim 3 obvious. Furthermore, Lilly claim 1 does not anticipate UW claim 3 as Lilly claim 1, taken in light of the prior art, fails to teach all the limitations of UW claim 3.

***18** Lilly claims 81 and 82 are directed to the coding sequence for the active light chain of human protein C. Lilly claim 81 does not specifically recite the structure of the coding sequence whereas Lilly claim 82 specifically sets forth the coding strand. The coding strand in Lilly claim 82 contains 465 base pairs, i.e., 155 codons. In contrast, UW claim 3 is directed to the cDNA encoding protein C and contains 1257 base pairs, i.e., 419 codons. The amino acid sequence of human protein C light chain, such as that recited in Lilly claim 81, and a particular DNA encoding that amino acid sequence, such as that provided in Lilly claim 82, do not provide sufficient information for one skilled in the art to predict the particular DNA sequence of UW claim 3. (Paper No. 17, p. 11, ¶ 21; Paper No. 27, p. 3, admitting UW facts 18-21). As Lilly claims 81 and 82 fail to teach or suggest the cDNA of UW claim 3, we conclude that UW claim 3 is patentably distinct from Lilly

claims 81 and 82.

C. Lilly's Corresponding Claims Are Patentably Distinct from UW Claim 1

UW claim 1 is directed to a plasmid or transfer vector that comprises cDNA coding for a human protein C. According to Lilly, there are two possible claim constructions for UW claim 1. (See, Paper No. 30, pages 4-5). First, Lilly contends that UW claim 1 must be construed as "limited to the specific allelic cDNA sequence disclosed in the UW '529 Patent, as is claim 3 of the UW '529 Patent" and that "claim 1 of the UW '529 Patent is essentially equivalent to claim 3 of the UW '529 Patent." (Paper No. 27, p. 7 and p. 9 and Paper No. 30, p. 4). Alternatively, Lilly argues that it is expected that UW will contend that claim 1 is generic and encompasses not only the cDNA sequence that UW discovered, but also the cDNA sequence discovered by Lilly. (See, Paper No. 27, p. 9). It is not necessary for us to determine whether UW claim 1 is as broad or as narrow as Lilly contends. There is no interference- in-fact under either claim construction. If we construe UW claims 1 and 3 as "essentially equivalent," there is no interference-in-fact as Lilly's corresponding claims do not teach or suggest the cDNA of UW claim 3 and would likewise not teach or suggest an "essentially equivalent" cDNA of UW claim 1. Specifically, Lilly's corresponding claims do not teach or suggest the particular number and location of the polymorphisms in the cDNA of UW claim 3 nor would they teach or suggest a such polymorphisms in a similarly construed claim.

If we construe UW claim 1 to be a generic claim covering any cDNA sequence that encodes human protein C, there is still no interference-in-fact. So construed, UW claim 1 would encompass thousands of possible sequences. Given such a vast number of possible sequences encompassed by a broadly construed UW claim 1, there would need to exist some suggestion or teaching in the prior art that guided one skilled in the art to the specific species claimed by Lilly. See In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994)(Prior art teaching of "vast number" of possible diphenol compounds did not teach or suggest the selection of Baird's claimed bisphenol A); In re Belle, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993)(DNA sequence would not have been obvious in view of prior art reference that taught a vast number of possibilities but did not teach or suggest why, among all those possibilities, one would seek the claimed sequence). The evidence presented fails to teach or suggest the selection of Lilly's claimed cDNA species from among the vast number of potential sequences that would be encompassed by a broadly construed UW claim 1. As UW claim 1, taken in light of the prior art, does not fairly teach or suggest Lilly's specifically claimed species, Lilly's claimed species are patentably distinct from a broadly construed UW claim 1. As a patentably distinct species is a "separate patentable invention" from its dominating genus, there is no interference in fact between a broadly construed UW claim 1 and Lilly's corresponding claims.

***19** Based on the facts presented, neither UW claim 1 nor UW claim 3 impedes the grant of Lilly's corresponding claims. Case, 730 F.2d at 750, 221 USPQ at 200. As UW's allegedly corresponding claims do not impede the issuance of Lilly's corresponding claims, there is no interference-in-fact. UW Preliminary Motion 1 for no interference-in-fact is granted.

3. Lilly Did Not Have Authorization to Set Its Own Time Period for Filing Motions to Add or Substitute a Count

Lilly had a full and fair opportunity to file motions responding to UW's motion for no interference-in-fact. Specifically, UW's motion was filed under Rule 633(b). Rule 633(i) permits a party to respond to such a motion by filing a motion to: (i) redefine the interfering subject matter (633(c)); (ii) substitute a different application (633(d)); or (iii) add a reissue application to the interference (633(h)). As such, Lilly had the opportunity to file a motion to redefine the interfering subject matter by adding or substituting a count or seek to have the claim correspondence changed. See, 37 CFR § § 1.633(b), (c) and (i). Rather than file a motion to add or substitute a count, Lilly stated that:

If this interference proceeds, further redefinition of the interfering subject matter would be necessary and desirable. For example, some modification of the Count itself will be necessary under 37 C.F.R. § 1.633(c)(1) so that it encompasses the subject matter of the involved Bang reissue claims currently designated as corresponding to the count. Otherwise, Lilly could be improperly denied the opportunity to present its best priority proofs. [Citation omitted]. Such modification of the Count is not necessary to resolve the interference-in-fact issue that is the subject of this special motion period, which merely turns on the "same patentable invention" relationship between the respective claims of the parties designated as corresponding to the Count. If a Preliminary Motion Period is set, Lilly will present an appropriate motion to modify the Count itself to exercise its right to have a count representing its "best proofs." In the same vein, Lilly will move during the Preliminary Motions Period to appropriately further modify the scope of the interference by designating the appropriate claims of the parties as corresponding to the Count.
(Lilly Preliminary Motion 1, Paper No. 22, p. 6, fn. 2).

Under the rules, a preliminary motion under § § 1.633 (a) through (h) shall be filed within a time period set by an APJ . Moreover, the time for filing motions under § 1.633 (i) is twenty (20) days after service of the initial motion under rule 633(a), (b), (c)(1) or (g), unless otherwise ordered by an APJ. 37 CFR § § 1.636 (a) and (b).

***20** In this case, an APJ set a specific time period for filing motions for no interference-in-fact or for judgment of unpatentability under 35 U.S.C. § 135(b). (Order, Paper No. 16). The APJ also set a specific time period for filing responsive rule 633(i) and (j) preliminary motions. (Order, Paper No. 16). As noted above, Lilly has chosen to sua sponte set its own schedule for submitting motions to redefine the interfering subject matter.

Lilly's failure to comply with the times set by the APJ undermines the APJ's ability to secure a "just, speedy, and inexpensive" determination of this interference. By failing to timely file its motions to redefine the interfering subject matter, Lilly has avoided the difficult and complex question of what a proper count and claim correspondence would be if this interference were to proceed. Further, if Lilly had timely filed its "necessary and desirable" motions to redefine the interfering subject matter, Lilly's motions may have provided additional evidence regarding the existence of an interference-in-fact or lack thereof. Lilly instead chose a more limited approach and is subject to the consequences of its choices.

4. The Panel Will Not Exercise Its Discretion Under Rule 641 to Review the Patentability of UW Claim 1

Lilly has argued that the issue of UW's written descriptive support for UW claim 1 is presently before the Board. This is not the case. Neither Lilly nor UW has briefed this particular issue. Moreover, as the panel has determined that there is no interference-in-fact between UW and Lilly, no Rule 1.633(a) patentability motions will be accepted from the parties. This is not to say that the panel has determined that UW claim 1 is patentable, but rather it is a recognition that Lilly will not be afforded the opportunity to submit unpatentability motions where there is no interference-in-fact. Berman v. Housey, 2002 U.S. App. LEXIS 10256 at *24 (Fed. Cir. 2002)(Refusal by Board to address issues of priority and patentability once it determined that there is no interference-in-fact is supported by sound policy considerations).

During the course of an interference, if an APJ become aware of a reason why a claim designated as corresponding to the count may not be patentable, the APJ has the discretion to enter an order notifying the parties of the reasons and set a time for each party to present its views. 37 CFR § 1.641. This interference was declared based, in part, on Lilly's allegations that a nucleotide sequence encoding protein C deposited by UW was identical to that of Lilly's. These allegations proved to be erroneous, albeit inadvertently. Given the circumstances of this interference, the panel chooses not to exercise its discretion under Rule 1.641 and explore the patentability or unpatentability of UW claim 1.

5. Lilly Contingent Miscellaneous Motion 2 is Moot

***21** Lilly filed a motion seeking leave to belatedly file a preliminary statement. (Lilly Contingent Miscellaneous Motion 2, Paper No. 41, p. 1). Lilly's motion is contingent on the determination that there is an interference-in-fact. As we have granted UW Preliminary Motion 1 for no interference-in-fact, Lilly's miscellaneous motion is moot.

6. Additional Comments

Lilly has argued that they have no other remedy in the USPTO. (Paper No. 27, p. 11). According to Lilly, a reexamination of UW's 529 patent is not available as Lilly's '624 patent was cited during the prosecution of UW's patent and UW overcame this rejection by filing a declaration under 37 CFR § 1.131. As such, Lilly concludes that the issue of Lilly's alleged work under § 102(g) should be resolved in an interference proceeding. Lilly also argues that the failure to recognize an interference-in-fact under the present circumstances leads to the "absurd, inequitable, and unlawful" result that Lilly's practice of its own prior invention may be alleged to infringe UW's claims.

The existence or nonexistence of another remedy within the USPTO is not a basis for continuing an interference where none exists. Should Lilly believe that an

actual controversy exists between the UW '529 patent and Lilly's activities, Lilly may file a declaratory judgment action in district court.

ORDER

Upon consideration of the motions, it is:

ORDERED that UW Preliminary Motion 1 for no interference-in-fact is granted.

FURTHER ORDERED that there is no interference-in-fact between claims 1 and 3 of UW, U.S. Patent No. 5,302,529 and claims 1-82 and 84-90 of Lilly, U.S. Application No. 09/185,663.

FURTHER ORDERED that Lilly Preliminary Motion 1 to designate an additional patent claim is moot.

FURTHER ORDERED that Lilly Contingent Miscellaneous Motion 2 for leave to belatedly file a preliminary motion is moot.

FURTHER ORDERED that if there is a settlement agreement, attention is directed to 35 U.S.C. § 135(c) and 37 CFR § 1.661.

FURTHER ORDERED that a copy of this final decision shall be placed and given a paper number in the file of Foster, U.S. Patent No. 5,302,529 and Bang, U.S. Application No. 09/185,663.

BOARD OF PATENT APPEALS AND INTERFERENCES

INTERFERENCE TRIAL SECTION

RICHARD E. SCHAFER

Administrative Patent Judge

RICHARD TORCZON

Administrative Patent Judge

MICHAEL P. TIERNEY

Administrative Patent Judge

FN1. A detailed discussion of the mechanism by which protein C down regulates blood coagulation is provided in Bang et al., U.S. Patent No. 4,775,624. (Ex 1018).

FN2. Rule 633(i) allows a party to respond to a motion for no interference in fact by filing, among other things, a motion under Rule 633(c) to redefine the interfering subject matter.

FN3. 730 F.2d 745, 221 USPQ 196 (Fed. Cir. 1984).

FN4. 547 F.2d 566, 192 USPQ 486 (CCPA 1977).

FN5. 537 F.2d 539, 190 USPQ 413 (CCPA 1976).

FN6. The decision in Nitz occurred prior to the merger of the Board of Interferences with the Board of Patent Appeals.

FN7. Specifically, the Federal Circuit stated:
Case challenges the declaration of the interference on the ground that no interference in fact exists. Relying on Nitz v. Ehrenreich, 537 F.2d 539, 190 USPQ 413 (CCPA 1976), Case argues that the question of interference in fact turns on whether or not the weight limitations present in the claims of Case's patent but omitted from the counts are material. We agree with this analysis but we see no departure by the board or the court in stating the law or applying it to the facts of this case.
Id.

FN8. While not specifically mentioned by Lilly, Lilly's relied upon comments were written in response to questions concerning whether or not the standard of patentability would be applied on a mutual basis in determining whether to add an additional count. Each count, of course, must be directed to a separate patentable invention. 37 CFR § 1.601(f). In other words, the comments responded to a question of whether the USPTO would require that Invention A be separately patentable from Invention B considered as prior art and Invention B be separately patentable from Invention A considered as prior art), in order for an interference to have both a species count and a genus count. The answer to this was no. Notice of Final Rules, 49 Fed. Reg. 48,416, 48432-434 (Dec. 12, 1984). Note, the test for no interference-in-fact and the addition of new count is essentially the same, i.e., patentable distinctness. See, e.g., Hester v. Allgeier, 646 F.2d 513, 521, 209 USPQ 370, 378 (CCPA 1982).

FN9. While Lilly's corresponding claims encompass several distinct species of cDNA, for reasons of convenience we refer to Lilly claims as "species" claims as opposed to "genus" or "subgenus" claims.

2002 WL 1305996 (Bd.Pat.App & Interf.)

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